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EASTERN DIVISION

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MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS'
MOTION TO EXCLUDE DAVID CUTLER'S OPINIONS AND PROPOSED
TESTIMONY**

July 31, 2019

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INTRODUCTION

Defendants move to exclude the opinions of Harvard economics professor Dr. David Cutler, but provide no sound basis under Rule 702 or *Daubert* to do so. Prof. Cutler's opinions analyze whether and to what extent the increase in prescription opioid shipments, including those caused by Defendants' manufacturing and distribution of prescription opioids, contributed to harms in the Bellwether Counties. *See* Report of David Cutler, Dkt. # 2000-4 ¶ 10 (the "Cutler Report"). In performing his calculations and analysis, Prof. Cutler adopted a framework rooted in well-recognized methodologies routinely used in the field of health economics.

Prof. Cutler's analysis is the middle step (of three) in Plaintiffs' quantification of causation and damages. In step one, Professor Meredith Rosenthal analyzed the relationship between Defendants' unlawful promotion of opioids and the increases in prescriptions of opioids that followed. She computed a percentage of increased prescriptions that could be attributed to Defendants' unlawful conduct. As part of this same step-one inquiry, the analysis of Dr. Craig McCann and James Rafalski computed the percentage of Defendants' shipments attributable to failures in the Defendants' suspicious order monitoring (SOM) systems. Together, the Rosenthal and Rafalski/McCann opinions quantify how Defendants' misconduct increased opioid shipments.

In step two, Prof. Cutler analyzes the relationship between opioid shipments and harms in the Bellwether Counties. Using the step-one analyses, and adding his own economic and econometric analyses, he computes a percentage of opioid-related harms attributable to Defendants' shipments of prescription opioids.¹ In the third step, Professor Thomas McGuire analyzes the costs the Counties incurred to address the opioid epidemic and, using the percentage found by Prof. Cutler, computes the share of those costs attributable to Defendants' misconduct and then computes the dollar value

¹ Prof. Cutler's analysis of prescription opioid shipments does not imply that his framework focuses solely on the conduct of distributors, as shipments are the manifestation of the Defendants' marketing and distribution misconduct. *See, e.g.,* Cutler Rep., Dkt. # 2000-4 ¶ 8 ("To be clear, for purposes of this report, the impact of prescription opioid shipments on harms to the Bellwethers includes all of defendants' misconduct ... including all defendants who used or endorsed deceptive marketing strategies and all defendants who failed to maintain effective controls over the distribution of prescription opioids.").

of the costs attributable to the Defendants. Thus, Plaintiffs' causal chain proceeds in three links: (1) Defendants' misconduct caused increased prescription opioid prescriptions and shipments; (2) increased opioid shipments caused increased opioid-related harms; and (3) increased opioid-related harms caused increased costs. Each expert focused only on one particular link in this chain (in Prof. Cutler's case, the middle link), but together these analyses show how Defendants' misconduct caused Plaintiffs' injuries and quantify the costs incurred as a result.²

Prof. Cutler's analysis itself consisted of three steps: (1) quantifying the share of harms in Bellwether Counties attributable to opioids; (2) quantifying the share of all opioid-related harms, including illicit harms, attributable to shipments of prescription opioids; and (3) quantifying the share of shipment-related harms attributable to Defendants' misconduct. Cutler Rep., Dkt. # 2000-4 ¶ 21. The results of these steps—each of which were computed using several data sets covering more than 20 years, including data directly from the Bellwether Counties—were multiplied to create annual estimates of the percentage of harms attributable to prescription opioid shipments. *Id.* ¶ 22. Every step taken by Prof. Cutler reflected reliable application of standard economic and econometric analysis commonly used in economic literature in general and health economics in particular.

Defendants nevertheless make four primary arguments for excluding Prof. Cutler's opinions.³ First, they argue that his methodology is unsound and unreliable. But, as described below, Prof. Cutler's methodology is widely recognized and accepted. He used a variety of regression analyses based on a comprehensive set of variables to show statistical relationships between prescription opioid shipments and opioid-related harms. Prof. Cutler provided detailed discussions of each and every

² The analyses described here do not provide Plaintiffs' only evidence of causation (*see* Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation), but they do provide important quantification of it, and of Plaintiffs' damages.

³ Defendants purport to categorize their challenges as pertaining either to reliability or to "fit," but the arguments they offer do not always align with the category in which Defendants have placed them. Rather than attempt to decipher what Defendants mean and what the significance of their arguments is, Plaintiffs will respond to the arguments *seriatim* in terms of both reliability and fit.

method underlying each of his regression analyses, the strengths and weaknesses of the data he used, the mechanics of his empirical estimation and their applicability, and their well-recognized usage within health economics. Courts have found such techniques to be reliable and admissible; any alleged shortcomings in the application of these analyses go to the weight rather than the admissibility of the testimony.

Second, Defendants challenge Prof. Cutler's opinions on the ground that they do not relate specifically to the Bellwether Counties and instead constitute impermissible "aggregate proof." But this is neither accurate nor germane. In fact, Prof. Cutler used data from a variety of national and state sources, including data directly from Cuyahoga and Summit Counties, to quantify opioid-related harms specifically in the Bellwether Counties. These analyses produce percentages of harms attributable to Defendants' misconduct that are specific to each county and year and take into account other factors that may have contributed to harms. Moreover, Plaintiffs have consistently represented to Defendants and the Court that they would likely pursue an aggregate theory of causation in this case, and Prof. Cutler's model reflects that approach. Whether this approach to causation is appropriate and sufficient in this case presents legal questions outside the scope of Defendants' *Daubert* motion.⁴ But Defendants' legal challenges to aggregate proof have no bearing at all on whether Prof. Cutler has reliably performed his analysis and do not implicate the Court's gatekeeping function under *Daubert*.

Indeed, as discussed below, in this instance, aggregate proof (coupled with the County-specific analysis mentioned above) is the proper way to establish causation. In order to examine and isolate the factors that could have caused the harms observed, it was necessary to study large data sets and to see whether the relationships observed between shipments and harms in the Bellwether Counties hold true elsewhere around the country. A single data point standing alone does not prove causation. It is

⁴ On the question of the sufficiency of Plaintiffs' aggregate proof, Plaintiffs respectfully refer the Court to their Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation.

the context of how strongly opioid shipments in counties all over the United States are correlated to harms in those counties that allows Prof. Cutler to make the causal inferences for the Bellwether Counties that he makes here.

Third, Defendants complain about Prof. Cutler's reliance on the analyses of Prof. Rosenthal and Dr. McCann. But this is no flaw – it is well-recognized that an expert may rely on other experts. Indeed, Plaintiffs' causation analysis was specifically structured so that the experts in each step would rely on the work of those in the prior step.⁵ Defendants also challenge *how* Prof. Cutler relied on and used the opinions of Prof. Rosenthal and Dr. McCann, but these challenges also lack merit and simply reveal that Defendants do not understand the structure of Plaintiffs' evidence. It is not any type of methodological flaw that Prof. Rosenthal did not compute harms in the analysis on which Prof. Cutler relies; that was not her job and such computation would have been out of place in step one of the causal chain. Prof. Rosenthal links Defendants' conduct to prescriptions, and Prof. Cutler then links the shipments resulting from the prescriptions to harms. Furthermore, Defendants' argument that Prof. Cutler's estimates of distributor and pharmacy misconduct are “unsupportable assumptions” ignore that Plaintiffs and Prof. Cutler made it unequivocally clear that he was relying on Dr. McCann's supplemental report, which was disclosed after Prof. Cutler's Report.⁶ Thus, Defendants have not shown, and cannot show, any reason that Prof. Cutler's reliance on these experts renders his opinions to be inadmissible.

Finally, Defendants argue that Prof. Cutler's analysis does not distinguish between effects of prescription opioids and effects of illicit opioids. But several of Prof. Cutler's analyses did precisely

⁵ To the extent Defendants challenge the specific opinions of those experts, including Prof. Rosenthal and Dr. McCann, those challenges lack merit, but are addressed in Plaintiffs' oppositions to the separate motions made with respect to those experts.

⁶ To the extent there is any ambiguity, as explained in more detail below, Plaintiffs provide revised computations reflecting the correct numbers, thereby resolving Defendants' claim that the percentages appear nowhere in Dr. McCann's Report. *See* Declaration of David Cutler in Support of Plaintiffs' Memorandum in Opposition to Defendants' Motion to Exclude David Cutler's Opinions and Proposed Testimony (“Cutler Decl.”) ¶¶ 9-10.

that. Prof. Cutler used regression analyses specifically to distinguish between (i) opioid-related harms attributable to shipments of *prescription* opioids and opioid-related harms that are not attributable to such shipments; and (ii) opioid-related shipments that are attributable to Defendants' misconduct and those that are not. In connection with these analyses, he also applied a comprehensive set of economic and demographic variables to account for other potential causes of increased opioid-related harms to conclude that *illicit* opioid-related harms were a direct consequence of prior prescription opioid shipments.

None of the Defendants' challenges to Prof. Cutler's careful and methodologically-sound analysis have merit. Their motion should be denied in its entirety.

LEGAL STANDARDS

In their motion to exclude Prof. Cutler's testimony, Defendants contest only the relevance or fit of Prof. Cutler's opinions to Plaintiffs' claims (*see* Defs.' Brief at 3-8), and the reliability of the methodology he used in forming those opinions (*id.* at 8-18), though as noted above Defendants often conflate and confuse the two in their analysis. Plaintiffs separately filed a *Daubert* Roadmap Brief setting forth the legal standards generally applicable to expert admissibility challenges, including the standards applicable for fit and reliability, and Plaintiffs adopt and incorporate herein by reference those general standards. *See* Plaintiffs' *Daubert* Roadmap Brief.

In addition to those standards, with respect to assessing reliability of an expert's methodology, the "inquiry envisioned by Rule 702 is . . . a flexible one." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594 (1993). Although *Daubert* identifies some indicia of reliability—testability, peer review, rate of error, general acceptance, *see id.* at 593-94—these "are neither definitive nor exhaustive." *Mike's Train House, Inc. v. Lionel, LLC*, 472 F.3d 398, 407 (6th Cir. 2006). Rather, the Court "must consider whether those factors are reasonable measures of reliability in a given case." *Id.* The Court thus "is not bound by any explicit test when determining reliability." *U.S. v. LaVictor*, 848 F.3d 428, 443 (6th Cir. 2017). Moreover, since Rule 702 focuses on an expert's methodology, an expert's testimony may

be reliable despite evidence supporting contrary conclusions: “*Daubert* neither requires nor empowers trial courts to determine which of several competing theories has the best provenance.” *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, No. 1:08-GD-50000, 2010 WL 1796334, at *3 (N.D. Ohio May 4, 2010) (quoting *Ruiz-Troche v. Pepsi Cola*, 161 F.3d 77, 85 (1st Cir. 1998)), *opinion modified on reconsideration*, 2010 WL 5173568 (June 18, 2010), *aff’d sub nom. Decker v. GE Healthcare Inc.*, 770 F.3d 378 (6th Cir. 2014).

ARGUMENT

I. PROFESSOR CUTLER IS HIGHLY QUALIFIED TO OFFER HIS OPINIONS REGARDING THE CAUSAL IMPACT OF PRESCRIPTION OPIOIDS TO HARMS.

While Defendants do not directly challenge Prof. Cutler’s qualifications, his expertise and credentials provide a useful lens through which to view the modeling he performed in this case. Prof. Cutler—the Otto Eckstein Professor of Applied Economics at Harvard—is widely regarded as one of the nation’s preeminent health economists. He has published hundreds of articles and written two books on the economics of healthcare, and has won multiple awards for his work in health economics. Cutler Rep., Dkt. # 2000-4 ¶¶ 2-3, App’x III.A. Particularly relevant here, Prof. Cutler has written extensively on issues related to population health and health changes over time, including measuring fatal and non-fatal health and economic factors – factors he has quantified in peer-reviewed articles using many of the same economic methodologies he employed in his Report. *Id.* ¶ 5. Prof. Cutler also has significant public sector experience, including as a Commissioner for the Health Policy Commission in Massachusetts, which has extensively studied the impact of opioid use. *Id.* ¶ 4.

Defendants’ own economist experts acknowledged that Prof. Cutler is “well regarded in the health economics community”,⁷ have characterized him as a “very smart academic researcher”,⁸ and

⁷ See Kevin Murphy Dep. (06/06/19) at 40:3-10, relevant portions of which are attached hereto as Exhibit A.

⁸ See Daniel Kessler Dep. (05/29/19) at 51:7-52:4, relevant portions of which are attached hereto as Exhibit B.

have “read many of the papers that [Prof. Cutler has] written and learned from them.”⁹ There is no question that Prof. Cutler is highly qualified to offer expert opinions in this case.

II. PROFESSOR CUTLER’S OPINIONS ARE RELIABLE, RELEVANT AND ADMISSIBLE.

Defendants’ attacks on Prof. Cutler’s opinions provide no basis to exclude them. Rather, as discussed below, these opinions are reliable and relevant within the meaning of Rule 702 and should not be excluded.

A. Professor Cutler Used Well-Recognized Methodologies to Create His Model and Arrive at His Opinions.

Prof. Cutler’s opinions are grounded in reliable methodologies and techniques widely accepted by economists and statisticians. As set forth above, Prof. Cutler’s analysis examined the effect of prescription opioid shipments on harms in the Bellwether Counties. Cutler Rep., Dkt. # 2000-4 ¶ 10. Prof. Cutler used a three-step analysis to estimate these harms, which consisted of analyzing (1) the share of harms attributable to opioids in the Bellwether Counties, (2) the share of opioid harms attributable to opioid shipments, and (3) the share of opioid shipments due to Defendants’ misconduct. *Id.* ¶¶ 21-23.

For step one of his analysis, Prof. Cutler used the same technique for estimating the share of harms attributable to opioids that has been extensively used in scientific literature for evaluating that question.¹⁰ Using these well-recognized approaches, Prof. Cutler specifically analyzed the share of a variety of harms in the Bellwether Counties attributable to opioids, including (1) the share of crime attributable to opioids, (2) the share of addiction and mental health activity attributable to opioids, (3) the share of children and family services due to opioids, (4) the share of juvenile court activity

⁹ *Id.*

¹⁰ As set forth in the Cutler Report, these include recently published and frequently cited literature evaluating the costs attributable to the opioid epidemic. Cutler Rep., Dkt. # 2000-4 ¶¶ 24-25 (citing, *e.g.*, Council of Economic Advisers, “The Underestimated Costs of the Opioid Crisis” (2017); Curtis S. Florence, Chao Zhou, Feijun Luo, and Likang Xu, “The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013,” 54 *Medical Care* 901 (2016)).

attributable to opioids, and (5) the share of medical examiner activity due to opioids. Cutler Rep., Dkt. # 2000-4 § IV, ¶¶ 32-46. These shares are expressed in a range of percentages for each applicable division in the Bellwether Counties beginning in 2006 and provide the first input into Prof. Cutler’s three-step analysis. *Id.*

For step two, Prof. Cutler used two different statistical models to analyze the relationship between prescription opioid shipments and all opioid-related mortality, including illicit opioid-related mortality. Cutler Rep., Dkt. # 2000-4 ¶¶ 26-27. These two approaches consisted of regression analyses—one of the most commonly used and widely-accepted forms of statistical and econometric modeling—which examined a robust set of shipment and mortality data from 400 counties over the course of 20-plus years, and also took into account a comprehensive set of economic and demographic variables in each county. *Id.* § V, ¶¶ 47-100. Prof. Cutler further explains the rationale for using these two models (a direct approach and indirect approach), the limitations of each model, and the basis for applying them over certain periods of time. *Id.* The results are expressed in a range of percentages from 1996-2016 that provide the second input into Prof. Cutler’s three-step analysis.

For his third step, Prof. Cutler incorporates estimates of the share of opioid-related shipments attributable to Defendants’ misconduct by relying on specific inputs provided by Prof. Rosenthal and Dr. McCann. Cutler Rep., Dkt. # 2000-4 ¶¶ 28, 101-117. As Prof. Cutler explains in his report, this step is necessary to differentiate “between estimates of the harm attributable to opioid shipments and harm attributable to shipments that resulted from misconduct by defendants.” *Id.* ¶ 28. These inputs provide the final percentages that Prof. Cutler multiplies with the prior two steps, which are then provided to Prof. McGuire to calculate the damages to the affected divisions in the Bellwether Counties. *Id.* ¶¶ 8, 101.

Finally, to supplement his analysis, Prof. Cutler adopted methodologies similar to those he used in step two of his analysis to examine the impact of prescription opioid shipments on criminal

activity. Cutler Rep., Dkt. # 2000-4 § VIII, ¶¶ 124-133. This empirical analysis established that such shipments did in fact lead to higher levels of crime, thereby confirming his determination that greater prescription opioid shipments led to increased harms. *Id.* ¶¶ 11, 124-133.

Each and every step of Prof. Cutler's analyses reflect economic and econometric methodologies that he himself routinely uses in his academic and governmental work, including in peer-reviewed studies and articles he has won awards for. Accordingly, as set forth in more detail below, Prof. Cutler's opinions are the product of fundamentally sound methodologies that he and others in the field of health economics regularly use in the academic and public policy settings, making them admissible in this case.

Defendants nevertheless raise a myriad of misleading, confusing, and conclusory arguments to suggest Prof. Cutler's analysis suffers from methodological flaws sufficient to bar his opinions altogether. *See* Defs.' Brief, § II.C at 8-18. None of these arguments provides a basis to exclude Prof. Cutler's well-reasoned and methodologically sound opinions regarding the impact of Defendants' prescription opioid shipments on harms.¹¹

1. *Professor Cutler Used a Comprehensive Set of Explanatory Variables For His Regression Analyses.*

For the direct and indirect regression analyses in connection with step two of his analysis, Prof. Cutler included a wide variety of different independent variables to control for other factors that impact opioid mortality, and adopted a "long difference" regression methodology when applying and analyzing these variables in his direct model – an approach widely used in economics. Cutler Rep., Dkt. # 2000-4 ¶¶ 84-86 (citing examples).¹² In particular, for his direct regression analysis, Prof. Cutler

¹¹ Plaintiffs discuss here Defendants' methodological challenges to the variables Prof. Cutler chose; his use of mortality; and his computation of the harms attributable to Defendants' misconduct. Defendants also argue that Prof. Cutler's use of national data, including data from 400 counties across the United States was improper. Because that argument relates less to methodology than to the applicability of Prof. Cutler's analysis specifically to the Bellwether Counties, Plaintiffs address that issue separately below, *see* Section II.B.

¹² The long difference methodology has specifically been applied to analyze, among other things, economic factors contributing to drug overdoses, the effect of crime on property values over time, and the impact of expanded trade with China on employment by industry and geography. Cutler Rep., Dkt. # 2000-4 ¶ 84. Prof. Cutler has also used this

used 45 different variables reflecting a variety of different county-specific economic and demographic characteristics that could influence mortality, including factors typically utilized in studies examining changes in mortality. *Id.* ¶¶ 88-92, App’x III.H; *see also* David Cutler Dep. (04/27/19), Dkt. # 1961-10 at 683:19-22 (“We included in the model all the variables that we could measure that either we or other studies suggested would have an impact on the mortality rate.”). Prof. Cutler’s direct regression analysis also produced a coefficient revealing how well the model is fitting the data, and he testified that “any economist who looked at a number like that in this context would feel like the model was a very good model.” *Id.* at 685:1-3.

With respect to his indirect regression analyses, Prof. Cutler similarly used variables to control for county-specific demographic and economic characteristics. Cutler Rep., Dkt. # 2000-4 ¶ 94, App’x III.H. Importantly, as discussed in Prof. Cutler’s Report and in further detail below, the indirect regression explicitly excludes shipments due to the changing nature of the crisis following 2010, when heroin and fentanyl mortality rates rapidly increased. *Id.* ¶¶ 76-80, 93-97. This shift is widely recognized in the literature, established in Prof. Gruber’s Expert Report, and also confirmed by Prof. Cutler through separate and independent regression analyses. *Id.* ¶¶ 50-63.

Defendants contend, however, that all of Prof. Cutler’s opinions should be excluded because the regressions he used in step two of his analysis suffer from omitted variable bias. Defs.’ Brief at 11. As an initial matter, the Supreme Court recognizes that the failure to include variables in a regression will affect the model’s probativeness rather than its admissibility. *Bazemore v. Friday*, 478 U.S. 385, 400, 106 S.Ct. 3000, 92 L.Ed.2d 315 (1986) (Brennan, J., concurring in part, joined by all Justices). Thus, a party cannot exclude a regression analysis simply by pointing to variables not taken into account. *Mebus v. Emporia State Univ.*, 222 F.R.D. 455, 462 (D. Kan. 2004); *Maitland v. Univ. of Minnesota*, 155 F.3d 1013, 1017 (8th Cir. 1998) (“[I]f a regression analysis omits variables, it is for the

methodology in his own peer-reviewed work, including in examining changes in suicide over time and the value of medical improvements over time. *Id.*

finder of fact to consider the variables that have been left out of an analysis, and the reasons given for the omissions, and then to determine the weight to accord the study's results”).

In addition, Defendants' specific complaint that Prof. Cutler “failed to include a control variable for the introduction of illicit fentanyl into illegal drug markets” (Defs.' Brief at 11) reflects yet another fundamental misunderstanding of Prof. Cutler's analysis, which was to examine whether the emergence of heroin and fentanyl was the *consequence* of prior shipments of prescription opioids. Thus, it is econometrically inappropriate to include “a control variable for the introduction of illicit fentanyl” in a regression model. *See* Cutler Decl. ¶ 48.

Defendants' additional contention that Prof. Cutler failed to use certain “deaths of despair” variables ignores that the variables he did apply are related to such deaths. For instance, in response to whether he considered the “deaths of despair” variables, Prof. Cutler testified that “some of the variables included in the model are likely to pick up some of these long-term issues [reflected in deaths of despair], and in fact, part of the reason for including them in the model is that they would pick up some of these long-term factors.” Cutler Dep., Dkt. # 1961-10 at 487:3-9. Furthermore, Prof. Cutler did include all the variables he had data on after an analysis of the underlying studies which discussed these deaths of despair. *Id.* at 557:9-16 (“[T]here was a discussion about were all of the issues associated with despair in different areas included in the models that Professors Case and Deaton and Professor Ruhm estimated, and as you noted correctly that not everything that one would like to have data on to measure despair we actually do have data on.”).

Defendants once again cite to their own expert reports to support their argument that Prof. Cutler failed to consider the proper variables. Defs.' Brief at 14 n.6. But differences between experts about which variables to select for regression analyses reflect differences in professional judgment, not any unreliability in the analysis. Indeed, “the selection of data inputs to employ in a model is a question separate from the reliability of the methodology reflected in the model itself.” *Manpower, Inc.*

v. Ins. Co. of Pennsylvania, 732 F.3d 796, 807 (7th Cir. 2013). Defendants' experts' use of different variables are therefore improper grounds to exclude Prof. Cutler's opinions, as they reflect competing theories that arrive at different results. *See In re Gadolinium*, 2010 WL 1796334, at *3.¹³ Thus, Defendants' arguments that Prof. Cutler's regressions omit certain variables—which are part of step two of his three-step analysis—provide no justification to exclude all of his opinions.

2. *Professor Cutler's Decision to Use Mortality as a Proxy For All Harms Is Reasonable and Reliable.*

As explained above, for step two of his analysis, Prof. Cutler focused on the relationship between shipments and harms, and in particular used opioid-related mortality as a proxy for harms. This mortality data, which is available at the county level for a more than 20-year time period, is the best and most comprehensive available data that reflects opioid-related harms. Indeed, as recognized by many of Defendants' own expert economists who frequently utilize this same opioid-related mortality data in their own research, the overall reliability of this data is not questioned in the research community. Cutler Decl. ¶ 66. The field of health economics also routinely studies how the use of substances—including addictive ones such as tobacco, alcohol, and more recently, opioids—are related to personal harms such as mortality. Cutler Rep., Dkt. # 2000-4 ¶ 14; Cutler Decl. ¶ 61.¹⁴ The choice of mortality as a proxy for harm is hardly controversial.

In addition, it is highly likely that measuring opioid-related mortality *underestimates* the impact caused by prescription opioid shipments at the county-level. For instance, in Prof. Cutler's

¹³ To the extent the Court gives any weight to Dr. Iain Cockburn's and Dr. Murphy's analysis cited by Defendants (*see* Defs.' Brief at 14 n.6), Defendants' experts' analyses are driven by their use of non-opioid drug overdoses in their analysis and their failures to understand the data utilized by Prof. Cutler. *See* Cutler Decl. ¶ 29. In addition, use of all the deaths of despair variables Defendants claim Prof. Cutler ignored actually results in substantially similar results. *Id.* This competing view of the data and how it can be interpreted is a classic example of competing expert theories that provide no basis for exclusion under *Daubert*.

¹⁴ *See, e.g.*, John Cawley and Christopher Ruhm, "The Economics of Risky Behaviors," in Handbook of Health Economics, Volume II 95 (Mark V. Pauly, Thomas G. McGuire, Pedro P. Barros ed., 2011); W. Kip Viscusi & Joni Hersch "The Mortality Cost to Smokers," 27 Journal of Health Economics 943 (2008); Christopher Carpenter & Carlos Dobkin, "The Effect of Alcohol Consumption on Mortality: Regression Discontinuity Evidence from the Minimum Drinking Age," 25 Journal of Economic Perspectives 133 (2011).

supplemental analysis between shipments and crime, Prof. Cutler's regression analyses yields a *higher* estimate of crime-related harms due to prescription opioid shipments than the relationship between shipments and opioid-related mortality, thus suggesting his primary conclusions are conservative. Cutler Rep., Dkt. # 2000-4 ¶¶ 124-133. As discussed in the Cutler Report, crime is also a key driver of opioid-related harms addressed by Bellwether Governments, including those addressed by law enforcement, courts, and jails. *Id.* ¶¶ 34-40. Opioid-related mortality is also conservative because it does not account for the amount of lives saved by naloxone. In fact, Cuyahoga County has administered approximately 15,000 doses of naloxone from 2015-2017, and the medical examiner estimates this has saved more than 2,000 lives during that same time period.¹⁵

Relatedly, Defendants contend that Prof. Cutler's evaluation of the impact of prescription opioid shipments on opioid-related mortality cannot be squared with Prof. Rosenthal's evaluation of the impact on detailing to opioid prescriptions. Defs.' Brief at 16. Defendants once again cite to their own expert report as the sole basis to support this purported methodological flaw. *Id.* As a preliminary matter, this argument repeatedly invokes a competing expert theory that provides no basis to exclude Prof. Cutler's opinions. In any event, the argument has no empirical basis. Both Prof. Cutler and Prof. Rosenthal track opioid activities on a morphine milligram equivalents (MME) basis and, as discussed in Prof. Cutler's report, Prof. Rosenthal's national data on prescription MMEs based on IMS data closely track shipments in ARCOS data used by Prof. Cutler, with an incredibly high correlation rate of 0.9973. Cutler Rep., Dkt. # 2000-4 ¶ 83; *see also id.* Data App'x at 16¹⁶. In addition, Defendants mischaracterize their own expert's results, which is *not* the same data relied on by Prof. Rosenthal. Cutler Decl. ¶ 78.¹⁷ As Prof. Cutler demonstrates, the data relied upon by Defendants'

¹⁵ See http://medicalexaminer.cuyahogacounty.us/pdf_medicalexaminer/en-US/HeroinFentanylReports/011119-HeroinFentanylReport.pdf

¹⁶ The Data Appendix was submitted manually to the Court on July 25, 2019. See Dkt. # 1999-4. Plaintiffs also attach it hereto in electronic form as Exhibit C.

¹⁷ Specifically, Defendants cite to Dr. Margaret Kyle's expert report to support this argument. But Dr. Kyle relies on a *different* database than Prof. Rosenthal – Prof. Rosenthal's analysis relies upon the IQVIA National Prescription Audit

expert reflect critical flaws which lead to far noisier results than the data he utilized, and thus significantly understate the relationship between prescriptions and harms. *Id.*

Tellingly, neither Defendants in their brief nor any of their experts in their reports offer an alternative to using mortality as a proxy for harm. But even if Defendants could present an alternative proxy for harm, there is no basis to exclude Prof. Cutler's opinions based on this reliable approach.

3. *Professor Cutler Reasonably Relies on Relevant and Available Data for His Analyses.*

As explained above, in order to estimate the share of harms that are due to opioids, Prof. Cutler's approach followed a well-worn path consistent with the general approach for evaluating costs attributable to the opioid epidemic. Cutler Rep., Dkt. # 2000-4 ¶ 25. Prof. Cutler specifically focused primarily on five areas: (1) crime; (2) addiction and mental health activity; (3) children and family services; (4) juvenile court activity; and (4) medical examiner activity. *Id.* ¶¶ 32-46. Defendants notably do not mention or challenge Prof. Cutler's general approach, or the majority of these specific analyses, but instead focus on two discrete criticisms to exclude the entirety of Prof. Cutler's opinions. Defs.' Brief at 17-18. Neither provides such a basis.

First, Defendants argue that Prof. Cutler's basis for the percentage of opioid-related harms due to criminal activity is unreliable. In particular, they claim the survey relied upon by Prof. Cutler regarding crime in general (and not opioid-related harms attributable to crime) is based on a faulty survey question. But this was the same specific approach to determine the share of drug-related crimes that are attributable to opioids used in published academic literature, including the data sources used for the estimation. Cutler Rep., Dkt. # 2000-4 ¶ 34. More importantly, Defendants grossly mischaracterize Prof. Cutler's analysis in saying he "does not use available crime data for Cuyahoga and Summit." Defs.' Brief at 17. This is flatly contradicted by Prof. Cutler's report, where he clearly

(NPA) Database, which is a national time series data on prescription based MMEs (*see* Plaintiffs' Memorandum in Opposition to Defendants' Motion to Exclude Meredith Rosenthal's Opinions and Proposed Testimony), while Dr. Kyle relies on the IQVIA Xponent database, which is based on a sample of prescription activity by physicians. *See also* Cutler Decl. ¶ 78.

uses Bellwether-specific data to measure the share of crime due to opioids. Cutler Rep., Dkt. # 2000-4 ¶¶ 35-37. In particular, for Summit County, he uses data from the FBI's National Incident-Based Reporting System which provides specific information on the number and type of criminal offenses that occurred within that county, as well as Prisoner Statistics from the Bureau of Justice to determine criminal activity which provide information on the distribution of crime. *Id.* Because similar data was not available for Cuyahoga, Prof. Cutler utilized data directly from the Cuyahoga County Prosecutor Database from 2009-2017 regarding the number of criminal charges in that county. *Id.*

Second, Defendants contend Prof. Cutler inappropriately relied on a single study from 2015 measuring the percentage of children taken into custody in 2015 in the Bellwether Counties. Importantly, this analysis is based on data published by the Public Children Services Association of Ohio (PCSAO) which reports the percentage of child removals in which opioids were being used specifically for Cuyahoga and Summit Counties. It is the best and most reliable data available for this metric (and indeed, Defendants and their experts do not present an alternative). For example, PCSAO Executive Director Angela Sausser testified to the Ohio Senate Health and Medicaid Subcommittee that the survey relied upon was intended to capture the percentage of children who were removed from their home due to opioids, and specifically identified which removals were due to opioids.¹⁸

Defendants also claim that Prof. Cutler's estimates of opioid-related addiction treatments are "speculative and unreliable" but provide no supporting evidence to support this claim. Defs.' Brief at 17-18. Instead, the data Prof. Cutler utilized are based on reliable spending for treatment of opioid abuse. For example, the Cuyahoga ADAMHS board reports spending for addiction services separately from spending on mental health services and reports whether Opioid Abuse/Opioid Type

¹⁸ See <http://advocatesforohio.org/perch/resources/PCSAO-Subcommittee-Testimony.pdf> (last visited on July 30, 2019). The PCSAO survey focused on removals where parental drug use was a removal factor and then identified which removals were due to opioids. Ms. Sausser specifically testified that "a survey my organization conducted showed that half of all children taken into custody in 2015 had parental drug use as a removal factor. Of those, more than half had parents using opioids, including heroin. That means 28% of children in custody that year were victims of this epidemic, and that number has almost certainly risen."

Dependence is the primary substance use diagnosis for each of individual treated for addiction.¹⁹ The Summit ADM Board's calculations are based on claims data for expenses incurred by individuals with opioid-related diagnosis, which again indicates these are expenses incurred as a result of opioids.²⁰

Thus, there is no basis for the Court to exclude all of Prof. Cutler's opinions based on purported methodological failures regarding two discrete analyses that are part of a multi-step analysis regarding step one of Prof. Cutler's three-step approach.

B. Professor Cutler Properly Used National Aggregate Data.

Defendants argue that Prof. Cutler's opinions should be excluded because his model draws on aggregate national data from 400 "large" counties and prescription opioid shipment and mortality rates in those counties—including the Bellwether Counties—to understand statistical trends for these variables in those counties. Defs.' Brief at 5-8. But the selection of these counties, which Defendants notably do not challenge, account for approximately 70% of both the U.S. population and all opioid-related mortality as of 2016. Cutler Rep., Dkt. # 2000-4 ¶ 90; *see also id.* Data App'x at 9. Using these 400 counties, Prof. Cutler then establishes the strong and statistically significant relationship between opioid-related mortality and prescription opioid shipments, including for example the high correlation rates and coefficients that reinforce the relationship. *Id.* ¶¶ 91-92. For shipments, Prof. Cutler derives his data from publicly available ARCOS data going back to 1997, the reliability of which Defendants likewise do not challenge. *Id.* ¶ 83.

Defendants suggest that the use of this national data makes Prof. Cutler's analysis both unreliable and irrelevant, but neither is true.²¹ In fact, Prof. Cutler's analysis is far more reliable *because*

¹⁹ *See, e.g.*, 2017 ADAMHS Annual Report at 8, 11 (CUYAH_000012577), *available at* http://adamhsc.org/pdf_adamhsc/en-us/Publications/ADAMHSCCRpts/17AnnualRpt.pdf.

²⁰ SUMMIT_001146951, attached hereto as Exhibit D.

²¹ Defendants don't consistently separate their reliability arguments from their fit arguments. For example, they suggest that Prof. Cutler's decision to use a national model is unreliable because their own expert opines that the Bellwether Counties had different levels of prescription opioid shipments and opioid-related mortality, Prof. Cutler's national model is unreliable. But this confuses apples and oranges – the methodology is reliable to measure what it measures. The question whether what it measures applies to this case if one of "fit."

he used a large sample set and did not rely solely on the data from the Bellwether Counties. Nor does the use of national data mean that Prof. Cutler's opinions don't "fit" the facts of this case. Prof. Cutler used the national data along with county-specific data to draw inferences informed by national trends, but tailored to the specifics of the Plaintiffs.

1. *Professor Cutler's Use of Aggregate National Data Is Reliable.*

Prof. Cutler's use of 400-county data makes his analysis more reliable, not less. As Plaintiffs explained in their opposition to Defendants' motion to exclude the opinions of Prof. Jonathan Gruber, the use of a large data set is critical to the ability to assess causal relationships. *See* Pls.' Mem. in Opp. to Defs.' Mot. to Exclude Jonathan Gruber's Opinions. Indeed, it would be almost impossible to make causal assessments based on examination of only a single case, or even two. An apparent relationship in one county could be a fluke or the result of unknown idiosyncrasies in that place. Only by examining a large number of places, to see whether the same relationship between shipments and harms can be discerned overall, can the analytic tools Prof. Cutler used provide reliable causation information. Thus, as Prof. Cutler's Report explains, the most appropriate way to assess the relationship between shipments and mortality is based on regression-based comparisons across a robust sample of counties across the nation, not just one or two counties viewed in isolation. *See* Cutler Rep., Dkt. # 2000-4 ¶¶ 81-100; Cutler Decl. ¶ 20; *see also Royal Park Invs. SA/NV v. U.S. Bank Nat'l Ass'n*, No. 14-civ-2590, 2017 WL 4748054, at *3 (S.D.N.Y. Oct. 19, 2017), *aff'd*, 349 F. Supp. 3d 298 (S.D.N.Y. 2018) ("[I]t seems axiomatic that the more data points that are available, the more reliable the ultimate damage calculation . . .").²²

A larger sample also reduces the potential for measurement errors specific to a geographic area, therefore making the extrapolation from this sample size a *better* fit to the Bellwether Counties. *See Reference Manual* at 246 ("Generally, increasing the size of the sample will reduce the level of random

²² Had Prof. Cutler only examined the Bellwether Counties, Defendants would undoubtedly attack his analysis on the basis that it would be economically inappropriate to ignore aggregate, national, or average trends regarding the impact of shipments to harms.

error . . .”). Indeed, researchers prefer using an average when analyzing a single area, as the variability inherent in using specific counties results in noisier trends, including if only the Bellwether Counties were used as Defendants suggest. Cutler Decl. ¶ 23. Moreover, examining a larger data set reduces (and not increases as Defendants suggest) the potential for measurement errors specific to any geographic area to distort impact estimates. Prof. Cutler’s use of data from 400 counties that covers 70% of the country over a period of 23 years measuring both prescription opioid shipments and opioid-related mortality is entirely reasonable and reliable.

Defendants’ argument that use of national data makes Prof. Cutler’s analysis unreliable also ignores that Prof. Cutler accounted for a large set of county-specific factors such as levels and changes in employment rates, age, gender demographics, and education, thereby driving down the potential measurement errors in his analysis. Cutler Rep., Dkt. # 2000-4 ¶¶ 82-100; *see also id.* App’x III.H; *see also* Cutler Decl. ¶ 25. Defendants simply argue that their own expert’s methodology—which only narrowly considers mortality and does not use the comprehensive list of factors used by Prof. Cutler—should prevail. But “Daubert neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance.” *Ruiz-Troche*, 161 F.3d at 85. As this Court previously observed, “Rule 702 is broad enough to permit testimony that is the product of *competing* principles or methods in the same field of expertise.” *In re Gadolinium*, 2010 WL 1796334, at *3 (emphasis added).

2. *Professor Cutler’s Use of Aggregate National Data Is Permissible and His Results “Fit” the Facts of this Case.*

Defendants also contend that Prof. Cutler’s aggregate model is “impermissible and irrelevant.” Defs.’ Brief at 7-8. They argue that his model does not “fit” Plaintiffs’ claims because it fails to isolate the harms in the Bellwether Counties and fails to isolate particular Defendants. *Id.* at 4 (“Despite specific allegations of unlawful marketing and distribution conduct . . . Cutler does not attempt to link

to any such conduct to any specific harms in the Track One Counties.”). Defendants are wrong on both counts.

It is no secret that Plaintiffs are pursuing an aggregate theory of damages in this case. Plaintiffs have made this clear throughout the litigation, and the Court has recognized Plaintiffs could pursue such a theory at trial. *See* Order re Discovery Ruling #5 (ECF Doc. 1047) (permitting Plaintiffs to respond to disputed interrogatories by stating that they “will rely, at trial and in expert opinions, solely on a theory of aggregate proof”). Although the Court has not yet determined the extent to which the use of aggregate proof in this case will meet Plaintiffs’ burdens at trial, courts routinely admit testimony based on aggregate methodologies. *See, e.g., Paige v. California*, 291 F.3d 1141 (9th Cir. 2002) (allowing plaintiffs to rely on aggregated data to show employment discrimination); *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 198 (1st Cir. 2009) (affirming district court’s denial of *Daubert* motion directed at expert’s aggregate damages methodology and noting “[t]he use of aggregate damages calculations is well established in federal court”); *Chen-Oster v. Goldman, Sachs & Co.*, 325 F.R.D. 55, 71 (S.D.N.Y. 2018) (admitting expert testimony that used aggregate analyses to demonstrate the impact of gender discrimination and acknowledging aggregate approach was merited in part based on “the statistical pitfalls of disaggregation”); *In re Lidoderm Antitrust Litig.*, No. 14-md-02521, 2017 WL 679367, at *28 (N.D. Cal. Feb. 21, 2017) (denying *Daubert* challenge to expert’s aggregate damages model where model was “based on reasonable assumptions and evidence, and supported by reasoned principles as well as academic scholarship”); *In re WorldCom, Inc. Sec. Litig.*, 02-civ-3288, 2005 WL 375314, at *7 (S.D.N.Y. Feb. 17, 2005) (admitting expert testimony regarding aggregate damages model).

Defendants’ “fit” argument ignores that Prof. Cutler did not rely *solely* on national-level data, but rather *also* looked at Bellwether-specific data for step one of his analysis. For example, in assessing the share of crimes attributable to opioids, Prof. Cutler looked specifically at criminal activity for “each

Bellwether and crime-related division.” Cutler Rep., Dkt. # 2000-4 ¶ 35. Prof. Cutler’s assessment of the increased share of addiction and mental health activity is similarly grounded in county-specific data. *Id.* at ¶¶ 41-42. The same is true for increases in the share of children’s and family services attributable to opioids, for increase in juvenile court activity, and increases in medical examiner activity. *Id.* at ¶¶ 43-46. His computations about the share of harms attributable to Defendants’ misconduct are specific to the Bellwether Counties. *Id.* at ¶¶ 118-123. As discussed above, the 400-county methodology reliably established that opioid shipments increase harms across the United States; Prof. Cutler’s county-specific analysis showed how that occurred in Summit and Cuyahoga Counties. Together, these analyses “fit” the facts of this case in the same way that medical opinions about general and specific causation (that an agent is capable of causing a harm and that it caused it in a particular person) are used together to establish causation.

Relatedly, Defendants contend that Prof. Cutler (1) fails to isolate what percentage of opioid prescriptions or shipments are linked to Defendants’ misconduct, (2) does not attempt to attribute harms to any particular Defendant, and (3) makes no effort to disentangle the effect of Defendants’ conduct from that of non-defendants. Defs.’ Brief at 4-5. These arguments once again ignore that evaluating the effect of Defendant misconduct is an *explicit* step in Prof. Cutler’s analysis. In any event, Prof. Cutler need not link particular shipments by particular Defendants to particular harms in order to establish that gross over-supply of opioids resulted in the harms of the opioid epidemic.

C. Professor Cutler Can Rely on the Inputs Provided to Him by Other Experts.

Defendants argue that Prof. Cutler’s reliance on other experts is improper and thus do not “fit” Plaintiffs’ claims. Defs.’ Brief at 2, 6-7.²³ Pursuant to Fed. R. Evid. 703, an expert’s testimony may be based on data and conclusions of other experts. *Asad v. Cont’l Airlines, Inc.*, 314 F. Supp. 2d 726, 740 (N.D. Ohio 2004); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 675 (6th Cir. 2010); *see also*

²³ Defendants repeat this argument when they claim Prof. Cutler’s analysis suffers from methodological flaws. *See* Defs.’ Brief at 8-9.

Williams v. Illinois, 567 U.S. 50, 88, 132 S.Ct. 2221, 2246, 183 L.Ed.2d 89 (2012) (Breyer, J., concurring) (“Experts . . . regularly rely on the technical statements and results of other experts to form their own opinions.”). For the reasons set forth in the opposition briefs to Defendants’ motions to exclude Prof. Rosenthal and Dr. McCann, their opinions are reliable and relevant. And as set forth above, Prof. Cutler incorporated these inputs into his analysis regarding the impact of prescription opioid shipments on harms in the Bellwether Counties. This was entirely appropriate.

Defendants argue, however, that because Prof. Rosenthal never analyzed the link between detailing and harms, it was improper for Prof. Cutler to input her results in his analysis. Defs.’ Brief at 7 (“Rosenthal attempts to analyze only the extent to which *all detailing* by Manufacturers collectively resulted in opioid prescriptions, not *harms*.” (emphasis in original)). Once again, Defendants fundamentally misunderstand and mischaracterize Plaintiffs’ causation and damage model. As described above, Plaintiffs’ causation analysis proceeds in three steps: promotion causes increases in prescriptions; increased shipments to fill those prescriptions causes increased harms; increased harms causes increased costs. Prof. Rosenthal and Prof. Cutler analyzed separate steps in the causal chain. Prof. Rosenthal’s analysis was limited to step one in the causal chain; once she assessed the extent to which promotion caused increases in prescriptions, it was up to Prof. Cutler to determine whether the increased shipments that filled those prescriptions caused increased harms. Thus, it is no criticism of Prof. Cutler’s use of Prof. Rosenthal’s work to say that she did not perform the same analysis he did.

Moreover, Prof. Rosenthal measured the impact of unlawful promotion on increased prescriptions by MMEs – the *same* measurement used by Prof. Cutler when subsequently analyzing the magnitude of prescription opioid shipments that caused harm. As explained above, there is an incredibly high correlation rate between the two sets of data. *See* Cutler Rep., Dkt. # 2000-4 ¶ 83, Data App’x at 16. Thus, Prof. Cutler’s reliance on Prof. Rosenthal is reliable and relevant.

Defendants' argument also ignores that the validity of Prof. Cutler's *model* does not depend on the particular inputs he received from either Prof. Rosenthal or Dr. McCann. The model would work just as well with other inputs. Indeed, Prof. Cutler provided the following opinion:

My methodology for computing annual estimates of the percentage of harms due to the defendants' misconduct would not be modified if the inputs are varied, so that if different percentages are assigned to the shipments attributable to the defendants' misconduct, the methodology can still be applied in estimating damages based on the modified calculations.

Cutler Rep., Dkt. # 2000-4 ¶ 11(5); *see also* Cutler Dep., Dkt. # 1961-10 at 598:6-593:3.²⁴ This is especially true because Dr. McCann, on whose analysis Prof. Cutler relied with respect to shipments that would have been flagged by various suspicious order metrics, provided two supplemental reports *following* the submission of Prof. Cutler's March 25 report. These supplemental reports explain the differences between the numbers that initially appeared in Prof. Cutler's report and those that appear in Dr. McCann's April 3 supplemental report. As Prof. Cutler's report makes clear, he specifically reserved the right to modify his analysis based on subsequently-served versions of any expert report quantifying the extent of distributor and pharmacy misconduct. *See id.* ¶ 9 n.8.²⁵ Prof. Cutler has entered Dr. McCann's new numbers into his model and recomputed his results using the new input. The revised computations are included in Prof. Cutler's Declaration, thereby resolving any ambiguity or concern raised by Defendants that Prof. Cutler's inputs are "unsupported assumptions." *See* Cutler Decl. ¶ 9.

²⁴ This model therefore takes into account the possibility that certain Defendants will not be part of the first Track One trial in October.

²⁵ Plaintiffs also made it abundantly clear to Defendants following the submission of Prof. Cutler's report where Defendants could determine the source of these inputs. *See* April 19, 2019 Correspondence from D. Ko to T. Knapp (attached hereto as Exhibit E) ("As the Cutler report makes clear (see para. 6 of Appx J) he is relying on other reports that provide the basis for the percentages that appear in that paragraph. In particular, the percentages are set forth in the McCann report and his supplements (see Table A of 4/3 McCann supplement) and also identified in section III of the Rafalski report.").

D. Professor Cutler Examined Differences between Harms Caused by Licit Opioids and Those Caused by Illicit Ones.

Defendants’ final claim that Prof. Cutler does not “even try to separate the impact from illicit drugs” (Defs.’ Brief at 5) is similarly unsupported.²⁶ In step two of his analysis, Prof. Cutler accounts for differences between licit and illicit drugs, and licit and illicit opioid-related mortality, through a series of regression analyses. *See* Cutler Rep., Dkt. # 2000-4 ¶¶ 64-80. These techniques are reliable and admissible, as regression analysis is considered a reliable discipline and admissible under Rule 702. *State of Ohio ex rel. Montgomery v. Louis Trauth Dairy, Inc.*, 925 F. Supp. 1247, 1252 (S.D. Ohio 1996) (citing *Petruszki’s IGA Supermarkets v. Darling–Delaware Co.*, 998 F.2d 1224, 1238 (3d Cir. 1993), *cert. denied*, 510 U.S. 994, 114 S.Ct. 554, 126 L.Ed.2d 455 (1993)); *see also City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 565-66 (11th Cir. 1998) (finding that expert testimony based upon multiple regression analysis utilized a methodology that was well-established as reliable); *Reference Manual on Scientific Evidence* (3d ed. 2011) (“*Reference Manual*”) at 308 (D. Rubinfeld, *Reference Guide on Multiple Regression*) (“*Multiple Regression*”) (“Because multiple regression is a well-accepted scientific methodology, courts have frequently admitted testimony based on multiple regression studies . . .”). Prof. Cutler’s use of these tools to differentiate between effects from licit drugs and effects from illicit ones belies Defendants’ argument that he failed to consider this distinction.

Moreover, the primary independent and explanatory variable in Prof. Cutler’s direct regression analysis is the shipment of *prescription opioids* (and not illicit drugs) based on publicly available ARCOS data going back to 1997, and their impact on opioid mortality through 2010. *See, e.g.*, Cutler Rep., Dkt. # 2000-4 ¶¶ 65-71; *see also id.* Data App’x at 11-18. Following 2010, as detailed in Prof. Cutler’s Report and through further regression analyses evaluating the changing nature of the opioid crisis, it would have been inappropriate to continue using a model that fails to account for changing determinants of

²⁶ While this and many of the attacks Defendants make in § II.A of their brief (*see* Defs.’ Brief at 3-8) are more appropriately arguments that Prof. Cutler’s model is purportedly unreliable, Plaintiffs address these arguments as Defendants have framed them, in terms of “relevance” or “fit.”

opioid-related harms – an opinion underscored in Prof. Gruber’s Report and recognized in economic and epidemiological literature. *Id.* ¶¶ 50-63; *see also* David Cutler Dep. (04/26/19), Dkt. # 1961-9 at 327:2-5 (“It would not be economically appropriate to estimate a model that goes past 2010” using shipment of opioids.).²⁷ For this later period, Prof. Cutler analyzed to what extent *pre-2010 shipments* of prescription opioids contributed to the rise in heroin and fentanyl mortality after that date, and to what extent that increase in mortality was caused by factors *other* than such shipments. These factors, as explained above, consisted of economic and demographic variables that could potentially have an impact on mortality. Thus, this second regression approach—the indirect approach described herein—intentionally *excluded* an examination of specific opioids manufactured and distributed by Defendants after 2010, because its purpose was to assess the contribution of other factors during this period.²⁸ Prof. Cutler therefore accounts for the differences between licit and illicit opioids by measuring the impact of pre-2010 prescription opioid shipments on post-2010 *illicit* opioid-related harms.

Defendants nevertheless argue that Prof. Cutler’s opinions do not match the theory of this case to the extent they are based on these indirect regressions (which Defendants call “unscientific indirect models”). *See* Defs.’ Brief at 5. But they do not argue that indirect modelling is itself unreliable (nor could they) and they do not explain why use of this reliable methodology results in a problem of “fit.” Indeed, indirect regression analyses are widely used in economics. Prof. Cutler himself and other authors of widely cited economic literature have used this methodology, including in an academic study for which Prof. Cutler received a prize for empirical economics. Cutler Rep., Dkt. # 2000-4 ¶ 80. Outside of healthcare, this purportedly “unscientific” method is also a standard

²⁷ *See also* Cutler Rep., Dkt. # 2000-4 ¶ 55 (citing to William N. Evans, Ethan Lieber & Patrick Power, “How the Reformulation of Oxycontin Ignited the Epidemic,” 101 *Review of Economics and Statistics* (2019) and Abby Alpert, David Powell & Rosalie Liccario Pacula, “Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids,” 10 *American Economic Journal: Economic Policy* 1 (2018)); *see also* Pls.’ Mem. in Opp. to Defs.’ Mot. to Exclude Jonathan Gruber’s Opinions.

²⁸ Had Prof. Cutler not analyzed such other factors, Defendants would no doubt complain that he ignored them.

framework used to assess macroeconomic productivity, economic analysis of wage differences and discrimination, and the effect of information disclosures on stock prices. *Id.* (citing to peer-reviewed studies). Whether considered as a question of “fit” or a question of reliability, Defendants’ argument should be rejected.

CONCLUSION

For the foregoing reasons, this Court should deny Defendants’ Motion to Exclude David Cutler’s Opinions and Proposed Testimony.

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Respectfully submitted,

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